STATE OF WISCONSIN Controlled Substances Board

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD

PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.40 relating to exclusion of [¹²³I]ioflupane.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

Statutory authority: s. 961.11 (4), Stats.

Explanation of agency authority:

961.11 (4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30–day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection and afford all interested parties an opportunity to be heard. At the

conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

Related statute or rule: s. 961.16, Stats.

Summary of, and comparison with, existing or proposed federal regulation: On September 11, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [¹²³I]ioflupane from schedule II of the federal Controlled Substances Act. The scheduling action was effective

September 11, 2015.

Plain language analysis:

The Controlled Substances Board did not receive an objection to excluding [¹²³I]ioflupane as a schedule II under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 13, 2015 to similarly exclude [¹²³I]ioflupane under chapter 961 effective October 19, 2015 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule amends 961.16 (2) (b), Stats. which excludes [123I]ioflupane from schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois does not exclude [123I]ioflupane from scheduling.

Iowa: Iowa excludes [123I]ioflupane from scheduling.

Michigan: Michigan does not exclude [123I]ioflupane from scheduling.

Minnesota: Minnesota does not exclude [123I]ioflupane from scheduling.

Summary of factual data and analytical methodologies:

The methodology was to remove [¹²³I]ioflupane from scheduling to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule excludes a drug from scheduling and does not have an effect on small business. Fiscal Estimate and Economic Impact Analysis: The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jeffrey.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on November 15, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.40 is created to read:

CSB 2.40 Exclusion of [¹²³I]ioflupane. Section 961.16(2)(b), Stats., is amended to read: (b) Coca leaves and any salt, compound, derivative or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [¹²³I]ioflupane is excluded from this paragraph. The following substances and any of their salts, esters, isomers and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)